Ethics Review Committee

Faculty of Medicine, Wayamba University of Sri Lanka

For office use only									
Application No	**PW**					**Date received**	D D	M M	Y Y Y Y

Names of the Reviewers

Reviewer 1	
Reviewer 2	
Reviewer 3	

Application for:

Research ☐
Establishment of Database ☐

Study type:

Intervention ☐
Non interventional ☐
Undergraduate project: MBBS ☐ BSc ☐

Part I

Title of the Project

2. Investigators

2.1 Principal investigator

Name	
Qualifications	
Designation	
Official address	
Telephone	
E-mail address	
Signature	

2.2 Other investigators 01/ Supervisor

Name	
Qualifications	
Designation	
Official address	
Telephone	
E-mail address	
Signature	

Other investigators 02/ Supervisor

Name	
Qualifications	
Designation	
Official address	
Telephone	
E-mail address	
Signature	

Other investigators 03/ Supervisor

Name	
Qualifications	
Designation	
Official address	
Telephone	
E-mail address	
Signature	

(If there are more investigators please use an additional sheet)

2.3 Is the principal investigator affiliated to the Wayamba University of Sri Lanka? ☐ Yes ☐ No

2.4 Are any of the other investigators affiliated to the Wayamba University of Sri Lanka? ☐ Yes ☐ No

2.5 Is ERC, FoM /WUSL the closest Ethics Review Committee to the study site? ☐ Yes ☑ No

2.6 Is this study industry sponsored? ☐ Yes ☐ No

*****If the answers to all above questions (2.3-2.6) are 'No', please note ERC, FoM /WUSL is unable to accept your application.**

3. Select all that applies to this study

a) Does this research involve collection or use of individual level data? ☐ Yes ☐ No

b) Are community level data on sensitive topics collected in this study ☐ Yes ☐ No

c) Are all data to be used in the research in the public domain? ☐ Yes ☐ No

d) Is this an audit carried out using existing data? ☐ Yes ☐ No

e) Are participants in this study considered as a vulnerable group? ☐ Yes ☐ No

f) Is the risk involved to the participants minimal? ☐ Yes ☐ No

g) Does the research involve use of biological material? ☐ Yes ☐ No

4. Nature of the research project

4.1 Specify the type of study

4.1.1 Observational/non interventional study:

Investigator initiated ☐

Industry sponsored ☐

4.1.2 Clinical trial:

Investigator initiated ☐

Industry sponsored ☐

4.1.3 Other interventional studies ☐

4.1.4 Research database

4.1.5 Other ☐

4.2 Is this for an academic degree? ☐ Yes ☐ No

4.2.1 If for an academic degree, specify:

4.2.2 Degree awarding University:				
4.2.3 Registration status	Registered	☐	Pending	☐
	Date of Registration			

5. Proposed dates of commencement and completion the study

[From initial recruitment of participants until completion of all data collection]

Date of commencement *Click here to enter a date.*

Date of completion Click here to enter a date.

6. Has ethical review for this study been requested earlier from <u>this</u> Ethics Review Committee? ☐ Yes ☐ No

If yes,

Reference number	
Decision*	
Date	

* Attach documentary evidence

7. Has ethical review for this study been requested from any other Ethics Review Committee? ☐ Yes ☐ No

If yes,

Reference number	
Decision *	
Date	

* Attach documentary evidence

☐ Yes ☐ No

8. Has this project been subjected to scientific review?

If yes,

Name and address of the committee	
Decision *	
Date	

* Attach documentary evidence

9. Estimated budget of your project*

Less than Rs.100,000 ☐

Rs.100,000 - Rs.300,000 ☐

Rs.300,000 - Rs. 1 million ☐

Rs. 1 million - Rs. 5 million ☐

Over Rs. 5 million ☐

*** Include budget in the proposal.**

10. Funding status

10.1 Status ☐ Planning to apply ☐ Decision pending ☐ Funding secured ☐ Self-funded

10.1.1 If funded:

Name & address of funding agency	
Amount	

10.2 Do study subjects got to incur any expenses by being participants in the study? ☐ Yes (Specify) ☐ No

11. Collaborative research

11.1 List the collaborating institutes and its role

	Institution	Recruitment	Lab facility	Logistics	Intellectual	Any other
1.						
2.						
3.						

* Attach documentary evidence.

11.2 Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s? If yes, ☐ Yes ☐ No

a)

Name and address of the committee	
Decision *	
Date	

b)

Name and address of the committee	
Decision *	
Date	

c)

Name and address of the committee	
Decision *	
Date	

* Attach documentary evidence

If no, give reason/s

11.3 What is the relevance of this study to Sri Lanka?

11.4 Are biological samples to be transferred abroad? ☐ Yes ☐ No

If yes,

a) Attach the material transfer agreement.
b) Describe the fate of the biological sample at the conclusion of the study

12. Intervention study

12.1 What phase clinical trial/intervention study is being conducted?

Phase I ☐
Phase II ☐
Phase III ☐
Phase IV ☐
Others (Specify) ☐

12.2 If it is a clinical trial, is it registered with a clinical trial registry (CTR)? ☐ Yes ☐ No

12.2.1 In which CTR is this registered?

Name of the registry	

***Please provide evidence of registration once it is completed**

☐ Yes ☐ No

12.3 Is it a multicenter trial?

If yes, list the other centers.

Country	Center	Effective date of joining the trial

12.4 Has ethical approval been obtained to conduct the study in centers given in 12.3 from relevant bodies? * ☐ Yes ☐ No

*If yes, attach documentary evidence

*If no, give justification

12.5 What is the procedure for dealing with adverse events?

12.6 What is the procedure for reporting adverse events?

*** Attach documentary evidence.**

12.7 What is / are the criteria for termination of the trial?

12.8 Are the participants paid? ☐ Yes ☐ No
If yes, amount of money per participant per visit?

12.9 Are the investigators paid? ☐ Yes ☐ No
If yes, by whom and the amount?

12.10 Details of insurance coverage for participants

***Attach documentary evidence.**

12.11 If Patient recruitment is not taking place in foreign collaborating institution explain why?

13. Conflicts of Interest

13.1 Declare any conflicts of interest that you may have in conducting this project (commercial/ financial/ intellectual/ other)

13.2 Does any member of the research team have any affiliation with the providers of funding/ support or financial interest in the outcome of research?
If yes, explain

☐ Yes
☐ No

14. Declaration of Applicant

1. As the Principal Investigator of this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
2. I understand that if there is any deviation from the project as originally approved, I must submit an amendment to the ERC for approval prior to its implementation.
3. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
4. I declare that I am not seeking approval for a study that has already commenced or has already been completed.
5. I will submit progress reports/reports of adverse events and side effects/ final report as requested by the ERC.

…… ……

Signature of the Principal Investigator Date

15. Consent from all investigators

We, the undersigned hereby confirm that we have consented to be co-investigators of the project titled
……
……
……
…….

Name	**Institutional Affiliation**	**Signature**

Part II – Protocol Checklist

Title of the Project:

		Page
1	Title	
2	Summary of the project	
3	Introduction/ background	
4	Objectives of the study	
5	Justification	
6	Review of literature	
7	Budget	
Methodology		
8	Study design	
9	Place of study	
10	Duration of the study	
11	Study population	
12	Sample size and calculation of sample size	
13	Inclusion criteria	
14	Exclusion criteria	
15	Study instrument/s	
16	Pilot study	
17	Sampling/ recruitment procedure	
18	Description of procedure	
19	Data collection	
20	Data analysis	
21	Maintenance and fate of data	
22	Dissemination of results	
Ethical issues		
23	Assessment of risks/ benefits	
24	Procedure for obtaining consent	
25	Informed consent form	
26	Participants Information sheet	
27	Justification for including vulnerable population	
28	Fair participant selection	
29	Procedures to protect the rights of participants	
30	Confidentiality/Privacy	

31	Voluntary participation right to refuse or withdraw without penalty	
32	Safety monitoring	
33	Responsibilities of the researchers	
34	Provision of medical and psychological support to participants	
Biological Samples		
35	Justification for using biological sample/s	
36	Procedures for collection, storage and disposal of biological sample/s	
37	Consent for collecting biological sample/s	
38	Protection of the rights of local collaborator	
39	Justification for transfer of data and /or biological/ genetic materials to the country of foreign collaborator	
40	Fate of transferred data and biological/ genetic material	
Clinical trial		
41	Investigator brochure	
42	Clinical record forms	
43	In case of multi centre studies listing of overseas centre(s) and ERC/IRB approval status if relevant and copies of ERC/IB approval letters from other centers	
44	Principle investigators'/ coordinating PI's curriculum vitae and evidence of Good Clinical Practice training	
45	Product liability letter or insurance certificate	
46	Patient recruitment procedures	
47	Patient's diary cards (if required in non clinical trial proposals as well) Justification for use of placebo	
49	Criteria for termination of participants from the trial	
50	Criteria for termination of the trial	
51	Adverse event monitoring, management and reporting	
52	Justification for withholding/ withdrawing standard therapy	
53	Provision for making the trial drug available after completion of the trial	

I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted and are in correct format. I hereby state that I have declare all conflicts of interests related to project financial or otherwise and I am not seeking approval for a study that has already commenced or has already been completed.

	DD	MM	YYYY
Date			

Signature of the Principal Investigator